

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 1954/PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/CH2004/000094	International filing date (day/month/year) 23.02.2004	Priority date (day/month/year) 23.02.2004
International Patent Classification (IPC) or national classification and IPC INV. A61B17/17		
Applicant SYNTHES AG CHUR et al.		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of 2 sheets, as follows:</p> <ul style="list-style-type: none"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in celectronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CH2004/000094

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-6 as originally filed

Claims, Numbers

1-11 received on 27.07.2005 with letter of 07.03.2005

Drawings, Sheets

1/2, 2/2 as originally filed

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-11
	No: Claims	
Inventive step (IS)	Yes: Claims	1-11
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-11
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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Re Item V.

1. The following documents are referred to in this communication:

D1 : US 5,766174

2. Independent claim 1

Document D1, which is considered to represent the most relevant state of the art, discloses an intramedullary nail (20) having a cylindrical proximal portion and a rectangular distal portion.

The subject-matter of independent claim 1 differs from the disclosure of D1 in that it contains further a proximal locking section (5) having the length L_5 and said first intermediate section (9) having the length L_9 are arranged at an angle β in the range $7^\circ < \beta < 13^\circ$.

The problem to be solved by the present invention may therefore be regarded as : "how to provide an intramedullary nail which can be adapted to various types of fractures".

The solution to this problem proposed in claim 1 of the present application, is to provide an intramedullary nail comprising three distinct locking sections which reduce the degree of freedom between the nail diameter and the intramedullary canal of the bone due to its isthmus locking section (see also the description p.5,§.3 to p.6, §. 1 and Figs. 2-5). Hence, the solution provided by the present application, to solve the problem to avoid the possibility of "play" in the system, was not obvious for the person skilled in the art.

Claims 2-11 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

3. The following defects were observed:

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

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International application No.
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Claims

1. Intramedullary nail (1) with a distal end (2) for insertion into the medullary canal, a proximal end (3), a central axis (4) and a generally rod-like shape over the hole length L ,

characterized in that

A) said nail (1) has three distinct locking sections (5,6,7) with at least one through-hole (8) each for receiving locking screws whereby said three locking sections (5,6,7) are separated from each other by two distinct intermediate sections (9,10) having less through-holes (8) per length unit than each of said locking sections (5,6,7); and
B) said proximal locking section (5) having the length L_5 and said first intermediate section (9) having the length L_9 are arranged at an angle β in the range of $7^\circ < \beta < 13^\circ$.

2. Intramedullary nail (1) according to claim 1, characterized in that said distinct intermediate sections (9,10) have no through-holes (8)

3. Intramedullary nail (1) according to claim 1 or 2, characterized by

A) a proximal locking section (5) extending from said proximal end (3) over the distance $0,22 L < L_5 < 0,28 L$ in direction of said distal end (2) and having a distal boundary (11);
B) a distal locking section (6) extending from said distal end (2) over the distance $0,18 L < L_6 < 0,22 L$ in direction of said proximal end (3) and having a proximal boundary (12); and
C) an isthmus locking section (7) located between said distal and proximal locking sections (5,6) with a proximal boundary (13) and a distal boundary (14) and a length of $0,08 L < L_7 < 0,15 L$.

4. Intramedullary nail (1) according to claim 3, characterized in that said proximal boundary (13) of said isthmus locking section (7) has a distance $0,27 L < L_9 < 0,33 L$ to said distal boundary (11) of said proximal locking section (5).

5. Intramedullary nail (1) according to claim 3 or 4, characterized in that said distal boundary (14) of said isthmus locking section (7) has a distance $0,13 L < L_{10} < 0,30 L$ to said proximal boundary (12) of said distal locking section (6).

6. Intramedullary nail (1) according to one of the claims 3 to 5, characterized in that $0,32 L < (L_{10} + L_6) < 0,50 L$.
7. Intramedullary nail (1) according to one of the claims 1 to 6, characterized in that it has a first intermediate section (9) having the length L_9 between said proximal locking section (5) and said isthmus locking section (7) and preferably having no through holes (8).
8. Intramedullary nail (1) according to one of the claims 1 to 7, characterized in that said it has a second intermediate section (10) between said distal locking section (6) and said isthmus locking section (7) having the length L_{10} and preferably having no through holes (8).
9. Intramedullary nail (1) according to one of the claims 1 to 8, characterized in that said isthmus locking section (7) has two through holes (8), preferably arranged at a relative angle α in the range of $60^\circ < \alpha < 120^\circ$.
10. Intramedullary nail (1) according to one of the claims 1 to 9, characterized in that the through hole (8) which is located nearest to said distal end (2) has a distance L_D to said distal end (2) in the range of $0,01 L < L_D < 0,38 L$.
11. Intramedullary nail (1) according to one of the claims 1 to 10, characterized in that the through hole (8) which is located nearest to said proximal end (3) has a distance L_P to said proximal end (3) in the range of $0,01 L < L_P < 0,70 L$.